ZUCKERMAN SPAEDER LLP

WILLIAM B. SCHULTZ *Pro hac vice motion forthcoming*
wschultz@zuckerman.com
MARGARET M. DOTZEL *Pro hac vice motion forthcoming*
mdotzel@zuckerman.com
COURTNEY CHRISTENSEN *Pro hac vice motion forthcoming*
cchristensen@zuckerman.com
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106

ASHFORD & WRISTON
A Limited Liability Law Partnership LLP

KEVIN W. HERRING 6722-0
kherring@awlaw.com
ROBERT I. PARK 11153-0
rpark@awlaw.com
First Hawaiian Center
999 Bishop Street, Suite 1400
Honolulu, Hawaii 96813
Telephone: (808) 539-0400

Attorneys for Amicus Curiae
AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF HAWAII

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, Defendant.	CIVIL 1:25-CV-00292-SASP-KJM MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS (DKT. 32) AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION (DKT. 11); EXHIBIT "A"; CERTIFICATE OF COMPLIANCE; CERTIFICATE OF SERVICE HEARING Date: _____ Time: _____ Judge: Hon. Shanlyn A.S. Park

MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS (DKT. 32) AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION (DKT. 11)

Amici Curiae American Hospital Association, 340B Health, Healthcare Association of Hawaii, and American Society of Health-System Pharmacists hereby move the Court for leave to submit their brief for the Court's consideration in connection with Defendant's Motion to Dismiss (Dkt. 32) and Opposition to Plaintiff's Motion for Preliminary Injunction (Dkt. 11). In support, *Amici* state and allege as follows:

1. This case raises important issues affecting matters of public health in this District.

2. *Amici* and their members have a strong interest in the resolution of the questions of law raised by the Plaintiff's Complaint and Motion for Preliminary Injunction and Defendant's pending Motion to Dismiss, in the particulars set forth in their brief.

3. The participation of *Amici* will assist and be useful to the Court in its evaluation of those issues and will not result in unfair prejudice to any party.

4. Counsel for *Amici* has advised the parties of their intention to file this brief. Defendant's counsel has represented that she consents to the filing of this *amicus* brief, and counsel for Plaintiff have not yet responded.

5. The proposed brief of *Amici* is attached to this Motion as Exhibit A.

WHEREFORE, *Amici Curiae* respectfully request that they be given leave to submit their brief in connection with Defendant's Motion to Dismiss (Dkt. 32) and Opposition to Plaintiff's Motion for Preliminary Injunction (Dkt. 11).

DATED: Honolulu, Hawaii; September 15, 2025.

*/s/*Kevin W. Herring
KEVIN W. HERRING
ROBERT I. PARK
Ashford & Wriston, LLLP

WILLIAM B. SCHULTZ*
MARGARET M. DOTZEL*
COURTNEY CHRISTENSEN*
Zuckerman Spaeder LLP

Attorneys for Amicus Curiae AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

EXHIBIT “A”

ZUCKERMAN SPAEDER LLP

WILLIAM B. SCHULTZ *Pro hac vice motion forthcoming*
wschultz@zuckerman.com
MARGARET M. DOTZEL *Pro hac vice motion forthcoming*
mdotzel@zuckerman.com
COURTNEY CHRISTENSEN *Pro hac vice motion forthcoming*
cchristensen@zuckerman.com
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106

ASHFORD & WRISTON
A Limited Liability Law Partnership LLP

KEVIN W. HERRING 6722-0
kherring@awlaw.com
ROBERT I. PARK 11153-0
rpark@awlaw.com
First Hawaiian Center
999 Bishop Street, Suite 1400
Honolulu, Hawaii 96813
Telephone: (808) 539-0400

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BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS (DKT. 32) AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION (DKT. 11)

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INTEREST OF *AMICI CURIAE*[1]

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Hawaii's legislative efforts to protect the 340B program.[2]

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

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[1] The Defendant does not object to the filing of this brief. Counsel for *Amici* reached out to counsel for Plaintiff regarding their consent and are still awaiting a response.

[2] Proposed *Amici* also certify that neither party's counsel authored the attached *amicus* brief in whole or part, and neither party nor its counsel nor any other person have contributed money to fund the preparation and/or submission of the brief.

The **Healthcare Association of Hawaii** (HAH) strives to create a healthy Hawaii, where every resident of every age has convenient access to appropriate, affordable, high-quality care, and where healthcare providers are reimbursed adequately to deliver that care.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

INTRODUCTION

Starting in 2020, nearly 40 drug companies, including members of Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA), broke with decades of precedent and suddenly refused to ship drugs purchased by 340B hospitals to contract pharmacies. The federal government determined that this was unlawful and sought to require manufacturers to continue delivering these drugs to

contract pharmacies on the same terms to which they delivered those drugs to 340B in-house hospital pharmacies.[3]

The drug companies (including PhRMA's members) fought that effort tooth and nail. In lawsuit after lawsuit, they argued that the federal government could not interfere with their contract pharmacy restrictions. At no point did the drug companies describe their contract pharmacy policies as price restrictions. Instead, they insisted that their policies were permissible because: (1) they were *delivery* restrictions,[4] and (2) the 340B statute had absolutely nothing to say about *delivery*. Those arguments carried the day. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703, 707 (3d Cir. 2023) (Section 340B's "text is silent about delivery" and "[l]egal duties do not spring from silence.").

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[3] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://www.hrsa.gov/sites/default/files/hrsa/opa/programintegrity/hrsa-letter-abbvie-covered-entities.pdf.

[4] *E.g.*, Novartis Opening Brief at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) ("Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies.") (emphasis added); AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

Now comes the whiplash. Banking the wins of those drug companies, PhRMA now contends that Hawaii's law requiring delivery to contract pharmacies regulates price, not delivery. And as part of that *volte-face*, PhRMA now insists that States cannot fill the federal statutory gap that other manufacturers have spent years fighting for in sister circuits. PhRMA's heads-I-win-tails-you-lose argument is as shameless as it is meritless.

This history is important—and not just because it exposes the hypocrisy in PhRMA's legal position. It also reminds the Court *why* Hawaii chose to step into the federal statutory void. Put simply, Hawaii acted because the other drug companies and the other federal courts all but invited it to. Faced with the drug industry's unprecedented assault on Hawaii's health care safety net and the acknowledged gap in federal law, the Hawaii legislature passed (Hawaii Act 143, which PhRMA refers to as H.B. 712). Act 143 does only what PhRMA and the federal courts said the *federal* law did not do—regulate the delivery of 340B drugs.

The primary issue here is whether Hawaii, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. Accordingly, PhRMA's claim fails.

First, Act 143 is not field preempted. "'[A] high threshold must be met' before a court will conclude that a federal law has impliedly preempted a state law." *In re*

Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prods. Liab. Litig., 959 F.3d 1201, 1212 (9th Cir. 2020) (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011)). Given that foundational principle, PhRMA's preemption arguments do not remotely approach the level necessary to overcome "'the assumption that the historic police powers of the States' are not preempted 'unless that was the clear and manifest purpose of Congress.'" *In re Volkswagen,* 959 F.3d at 1212. (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)).

Congress did not create or occupy any field through its 340B legislation. *E.g., PhRMA v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) *cert. denied*, 145 S. Ct. 768 (2024); *AbbVie v. Fitch*, 2025 WL 2630900 at *7 (5th Cir. September 12, 2025) (unpublished); *Abbvie v. Skremetti*, 2025 WL 1805271 at *13 (M.D. Tenn. June 30, 2025) (collecting cases). PhRMA's entire field preemption argument hinges on the false notion that "Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS." Complaint (Compl.) (ECF No. 1) ¶ 119. But comprehensiveness alone does not wrest traditional police power from the States. That has never been the rule in our federal system. *E.g.*, *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 717 (1985); *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990); *N.Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). And even if it were, the 340B statute is silent as to delivery of 340B drugs and contract pharmacies. As numerous courts across the country have

recognized, this gap in federal law is fatal to any field preemption claim. *E.g.*, *PhRMA v. McClain*, 95 F.4th at 1143–45 (8th Cir. 2024), *AbbVie v. Fitch*, 2025 WL 2630900 at *6 (5th Cir. September 12, 2025); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 747 (S.D. Miss. 2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507, at *4–9 (S.D. Miss. Dec. 23, 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881, at *2–4 (W.D. Mo. Feb. 13, 2025).[5]

Second, Act 143 is not conflict preempted. Contrary to PhRMA's assertions, Hawaii's law does not transform contract pharmacies into "new 340B entities"; it does not contravene the federal government's enforcement authority; and it does not regulate 340B price. *See AbbVie v. Fitch*, 2025 WL 2630900 at *7-8 (5th Cir. September 12, 2025); The price of 340B drugs continues to be set by federal law. Hawaii's law only affects *where* the 340B drugs (purchased by 340B hospitals) are shipped and stored. It is, in essence, a non-discrimination provision. Act 143 allows *Hawaii* hospitals to choose where 340B drugs are to be shipped for its patients (a hospital pharmacy or a contract pharmacy), rather than letting drug companies discriminate in favor of in-house hospital pharmacies. What's more, State

[5] The only court to conclude that the drug manufacturers were likely to succeed on the merits of their preemption claim based its ruling on a fundamental misunderstanding of the 340B statute and program. *See PhRMA v. Morrissey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024).

enforcement is limited to *only* this non-discrimination requirement. Hawaii does not enforce requirements under federal law; it enforces only the state law requirement under Act 143 that AbbVie deliver drugs (bought by Hawaii's 340B hospitals) to contract pharmacies *on the same terms* as they deliver to Hawaii's in-house hospital pharmacies.

All in all, PhRMA's attack on Act 143 is really an attack on federalism itself. At bottom, PhRMA tries to transform an acknowledged federal statutory silence into a reason to displace traditional state authority. That is not the law in this Circuit. *See In re World Auxiliary Power Co. v. Silicon Valley Bank*, 303 F.3d 1120, 1131 (9th Cir. 2002) ("There is no reason to infer from Congress's silence … an intent to … preempt[] state law …. [t]hat would amount to a presumption in favor of federal preemption, but we are required to presume just the opposite."). Nor is it the law elsewhere.[6]

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[6] *See, e.g., Conway v. United States*, 997 F.3d 1198, 1211 (Fed. Cir. 2021) ("Congress' silence is powerful evidence that Congress did not intend to preempt state law fixing creditors' rights during insolvency." (citation and internal quotation marks omitted)); *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 985 (7th Cir. 2012) ("As we have noted, congressional and regulatory silence usually *defeats* a claim of preemption, not the other way around.") (emphasis in the original); *Iowa, Chi. & E. R.R. Corp. v. Washington Cnty.*, 384 F.3d 557, 561 (8th Cir. 2004) ("ICCTA did not address these problems. Its silence cannot reflect the requisite clear and manifest purpose of Congress to preempt traditional state regulation of public roads and bridges that Congress has encouraged in numerous other statutes." (citation and internal quotation marks omitted)); *Schafer v. Am. Cyanamid Co.,* 20 F.3d 1, 6 (1st Cir. 1994) ("Pre-emption law, for example, cautions us against finding that a congressional act pre-empts a state law through

"Pharmacy has traditionally been regulated on the state level." *McClain*, 95 F.4th at 1144. When the text of the law regulates for health and safety, the Court may only "deem the statute preempted" if "Congress's intent to preempt the challenged state statute is 'clear and manifest.'" *Puente Arizona v. Arpaio*, 821 F.3d 1098, 1104 (9th Cir. 2016) (citing *Wyeth*, 555 U.S.at 565). No such intent is evident here. It certainly is not made clear through statutory silence. Thus, invalidating Hawaii's lawful exercise of State authority would turn upside down the very "federalism concerns" that underlie preemption questions and upend "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

FACTUAL BACKGROUND ON THE IMPORTANCE OF CONTRACT PHARMACY ARRANGEMENTS IN HAWAII

PhRMA spends page after page maligning the 340B Program and the covered entities that rely on it. Needless to say, it is in its financial interest to do so. For

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silence." (citing *Maryland v. Louisiana,* 451 U.S. 725, 746 (1981)); *Paul v. Monts,* 906 F.2d 1468, 1475 n.8 (10th Cir. 1990) ("Congressional silence will not be presumed to mandate preemption. On the contrary, it will not be presumed that a federal statute was intended to supersede the exercise of the power of the state unless there is a clear manifestation of intent to do so.") (citation and internal quotation marks omitted); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 616 (1997) (Thomas, J., dissenting) ("[E]ven where Congress has legislated in an area subject to its authority, our pre-emption jurisprudence explicitly rejects the notion that mere congressional silence on a particular issue may be read as preempting state law.").

PhRMA's members, every 340B drug it refuses to deliver to a Hawaii contract pharmacy is an additional profit line on its balance sheets.

But this is not how the Supreme Court has viewed the program. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). And more significant here, the Hawaii legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, shares the Supreme Court's view of the Program. When enacting Act 143, the Hawaii legislature rejected the drug companies' efforts to denigrate the 340B Program and those who rely on it.

For good reason. The contract pharmacy arrangements that PhRMA's members honored for almost 30 years helped sustain hospitals and their patients. Nationwide, a quarter of hospitals' 340B benefit comes from drugs dispensed at contract pharmacies.[7]

340B savings allow hospitals to care for Hawaii's most vulnerable patients in a variety of ways. Look no further than the many declarations submitted with Defendants' Memo in Opposition to the Motion for Preliminary Injunction in

[7] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

AbbVie v. Lopez, 25-cv-230 (D. Hawaii) (ECF No. 26). Together and separately, these declarations tell a powerful story: without the benefit they obtain from drugs delivered to community pharmacies, 340B hospitals and Federally Qualified Health Centers will have to curtail vital healthcare services or eliminate them entirely. Hawaii patients will become sicker as PhRMA's members gets richer.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[8] Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many insurers require for the dispensing of "specialty" drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.[9] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy outside of its in-house pharmacy.[10] Denied these and

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[8] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[9] Adam J. Fein, Drug Channels Institute, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?* (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html; Specialty Drug Coverage and Reimbursement in Medicaid, HHS Office of Inspector General, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[10] 340B Health, *supra* note 7, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*

other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services.[11]

Big Pharma's assault on contract pharmacy relationships drastically reduces the savings that Hawaii's 340B hospitals rely on and jeopardizes the hospitals' ability to provide valuable services to their patients.

ARGUMENT

I. PHRMA'S CLAIMS ARE MERITLESS BECAUSE ACT 143 IS NOT PREEMPTED.

"The purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (citation omitted). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,'" *Medtronic, Inc.* 518 U.S. at 485, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002). That is "particularly" true in "matters of health," given "the historic primacy of state regulation" in that area. *Medtronic, Inc.*, 518 U.S. at 485. PhRMA cannot satisfy its "burden of overcoming th[e] presumption" against

(Mar. 2022)) https://drugchannelsinstitute.com/files/2022-PharmacyPBM-DCI-Overview.pdf.

[11] *Id.*, 340B Health at 2, 5.

preemption. *PhRMA v. Walsh*, 538 U.S. 644, 662 (2003). This Court should reject each of PhRMA's myriad preemption theories—just as numerous district courts as well as the Eighth Circuit have done with preemption challenges to substantially similar state contract pharmacy statutes.[12]

A. Congress did not create or occupy a field in the 340B statute.

PhRMA's field-preemption theory both misapplies the relevant standard and mischaracterizes the 340B statute. Field preemption occurs only in narrow circumstances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. NCAA*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs.*, 413 U.S. at 415. Thus, the Supreme Court has "reject[ed] . . . the contention that pre-emption is to be inferred merely from the comprehensive character" of a federal statute. *Id.; see AbbVie v. Fitch*, 2025 WL

[12] *See PhRMA v. McClain*, 95 F.4th at 1143–45; *PhRMA v. Murrill*, 2024 WL 4361597, at *8; *see also, e.g.*, *Abbvie v. Skremetti*, No. 3:25-cv-00519; 2025 WL 1805271, at *16 (M.D. Tenn. June 30, 2025); *Novartis v. Fitch*, 738 F. Supp. 3d at 747; *AstraZeneca v. Fitch*, 2024 WL 5345507, at *4–9; *Novartis v. Bailey*, 2025 WL 489881, at *2–4.

2630900 at *6 (5th Cir. September 12, 2025) (unpublished) ("Field preemption 'should not be inferred, however, merely because the agency's regulations are comprehensive.'" (quoting *R.J. Reynolds Tobacco Co. v. Durham County*, 479 U.S. 130, 149 (1986)). Rather, a statute preempts an entire field only if it "reflect[s] a congressional decision to foreclose any state regulation in the area," and thus "confer[s] a federal right to be free from any other" requirements in the same field. *Murphy*, 584 U.S. at 479 (citation omitted).

PhRMA's field-preemption theory relies entirely on the (supposed) comprehensiveness of the 340B statute, its dispute-resolution system, and its relationship to the Medicaid program. *See* Compl. ¶ 120 (alleging that, in the 340B statute, "Congress designed a pervasive and integrated scheme of regulation"); Pl.'s Mem. in Supp of Pl.'s Mot. for Prelim. Inj. (Pl.s' MPI at 12) (ECF No. 11-1). But PhRMA is simply wrong to characterize the 340B statute as "comprehensive." *Id.* ¶ 119. "Section 340B does not 'provide a full set of standards governing' discounted drugs for needy patients… Notably, it regulates neither the distribution of drugs to patients nor the role of pharmacies in this distribution." *AbbVie v. Fitch*, 2025 WL 2630900 at *6 (5th Cir. September 12, 2025) (unpublished) (collecting sources).

PhRMA should know this: PhRMA and many of its members ferociously argued, and convinced federal courts, that the 340B statute is "silent about delivery conditions." *Novartis v. Johnson*, 102 F.4th at 460. And for precisely that reason,

the Eighth and Fifth Circuits (the only circuits to address challenges to similar state statues) and numerous district courts concluded that the 340B statute is *not* comprehensive and rejected a field preemption challenge to a state contract pharmacy statute substantially similar to Act 143. *See PhRMA v. McClain*, 95 F.4th at 1143 ("Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field."); *AbbVie v. Fitch*, 2025 WL 2630900 at *6-7 (5th Cir. September 12, 2025) (unpublished); *PhRMA v. Murrill*, Nos. 6:23-CV-00997, 6:23-CV-01042, 6:23-CV-01307, 2024 WL 4361597, at *8 (W.D. La. Sept. 30, 2024) ("Section 340B is silent with respect to contract pharmacies, and Plaintiffs have not pointed to any provisions in the statutes governing the Medicare or Medicaid programs that address [contract] pharmacies"); *see also id.* ("it is unclear to the Court how the interrelationship between Section 340B and the Medicare and Medicaid programs requires uniformity with respect to contract pharmacies when none of these statutes address contract pharmacies"). This Court should follow the Eighth and Fifth Circuit's (and several district courts') reasoning and reject PhRMA's field preemption theory here.

B. Act 143 does not conflict with the 340B statute.

The Court also should follow the Eighth and Fifth Circuits and a growing chorus of district courts in rejecting PhRMA's conflict preemption theories. *E.g., PhRMA v. McClain*, 95 F.4th at 1144–45; *AbbVie v. Fitch*, 2025 WL 2630900 at *7-

8 (5th Cir. September 12, 2025) (unpublished). A proper conflict preemption analysis requires parties to demonstrate that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is a "high threshold," *Chamber of Com. of U.S.*, 563 U.S. at 607, and PhRMA comes nowhere close to meeting it.

The 340B statute was passed to help covered healthcare providers "reach[] more eligible patients and provid[e] more comprehensive services." HRSA, *Final Rule, 340B Drug Pricing Program; ADR Regulation*, 89 Fed. Reg. 28,643, 28,643 (Apr. 19, 2024) (hereinafter, "ADR Rule"). Hawaii Act 143, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients. Act 143 Section 1. Thus, not only does Act 143 not stand as an obstacle to the purposes of the 340B statute, "it does the opposite: [Act 143] assists in fulfilling the purpose of 340B." *PhRMA v. McClain*, 95 F.4th at 1144–45; *see also CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 83 (1987) (rejecting conflict preemption challenge because, although state statute imposed additional rules in an area heavily regulated by a federal statute, it "further[ed] the federal policy" embodied by the federal statute).

More specifically, PhRMA proffers several ways in which Act 143 purportedly conflicts with the federal 340B statute. Each of PhRMA's arguments fails.

1. *Act 143 does not expand the scope of 340B's federal requirements.*

The crux of PhRMA's attack on Act 143 is that it expands the scope of 340B's federal requirements. Compl. ¶ 126. According to PhRMA, Act 143 aims "to compel drug manufacturers to make 340B-priced sales in situations and under circumstances that federal law does not require." *Id*. ¶ 128 (emphasis omitted). However, this argument is "simply incorrect." *AbbVie v. Fitch*, 24-60375 at *7 (5th Cir. September 12, 2025) (unpublished).

There are no federal requirements regarding delivery. *Novartis*, 102 F.4th at 461. Critically, Act 143 does *not* set the price of any drug sales. Instead, Act 143 sets forth Hawaii's own requirements, with their own consequences. The federal 340B statute dictates what price manufacturers must offer (the "ceiling price") and to whom (340B "covered entities"). 42 U.S.C. §256b. Act 143 does not alter either requirement. As the Fifth Circuit correctly realized when addressing an analogous state law:

> By its plain text, H.B. 728 requires drug manufacturers to give custody of discounted drugs to contract pharmacies only insofar as they have partnered with covered entities to distribute the drugs to patients. It does not compel manufacturers to "offer" discounted drugs to contact pharmacies in the way that Section 340B compels them to "offer" these drugs to covered entities.

AbbVie v. Fitch, 24-60375 at *7 (5th Cir. September 12, 2025) (unpublished). Simply put: "[Chapter 288] does not set or enforce discount pricing." *PhRMA v.*

McClain, 95 F.4th at 1145; *see also PhRMA v. Murrill*, 2024 WL 4361597, at *9 ("[D]iscounts are set by the federal government, not the State of Louisiana or Act 358. Act 358 addresses only contract pharmacies, a matter that is not addressed in Section 340B.").

Act 143's core provision states only that a drug company may not limit a 340B drug's (which the statute defines as a "drug that is purchased by a 340B covered entity through the federal 340B drug pricing program") acquisition by, or delivery to, "a pharmacy that is under contract with a 340B covered entity and is authorized under the contract to receive and dispense 340B drugs *on behalf of the 340B covered entity*." Act 143 §§1, 2(a) (emphasis added). Put another way, Act 143 bars drug companies from discriminating against Hawaii 340B hospitals based on their chosen delivery location. It simply requires drug companies to allow covered entities to be treated like any other purchaser of those drugs, with the same freedom to select where their drugs will be delivered. *See PhRMA v. Fitch*, No. 1:24-cv-160-HSO-BWR, 2024 WL 3277365, at *11 (S.D. Miss. July 1, 2024) ("While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs . . . , Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs."); *id.* at *9 ("House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to

pharmacies for distribution—something Section 340B may not require but does not implicitly preclude either.").

Relying on the Third Circuit and D.C. Circuits' decisions in *Sanofi* and *Novartis*, *Sanofi Aventis U.S. LLC,* 58 F.4th at 703; *Novartis Pharms. Corp. v. Johnson,* 102 F.4th at 460, PhRMA argues that Act 143 interferes with the conditions it was permitted to place on its "offer" to sell 340B drugs to 340B covered entities. Pls. MPI at 17-18. But those decisions are not to the contrary. *PhRMA v. Murrill*, 2024 WL 4361597, at *8. While those courts permitted *drug companies* to place some reasonable conditions in the face of the federal law's "silence" about delivery, neither court addressed what the *States*, armed with their historic police powers over health and safety, may do in the face of that silence. *Sanofi Aventis U.S. LLC,* 58 F.4th at 703; *Novartis Pharms. Corp. v. Johnson,* 102 F.4th at 460.

2. *Act 143 does not impede the federal audit and ADR process through minor restrictions on claims data.*

PhRMA's complaint that Act 143 poses an obstacle to the Federal ADR and audit process relies on a misleading description of the process. Under the 340B statute, a manufacturer must audit a covered entity before initiating the statute's administrative dispute resolution ("ADR") process. 42 U.S.C. § 256b(d)(3)(B)(iv). According to PhRMA, Act 143's restriction on demanding certain types of data from covered entities "limits manufacturers' ability to collect the very data necessary to obtain an audit" under the 340B statute because it prevents them from establishing

"reasonable cause" to suspect that a covered entity is violating its statutory obligations—which manufacturers must do before conducting an audit. Pls. MPI at 22-23.

However, to the extent the Act 143 does prohibit access to data, it does not interfere with the 340B statute's audit and ADR process. As HRSA has explicitly stated, the threshold that a drug manufacturer must meet when seeking HRSA's approval to audit a 340B entity is "*not overly burdensome*" and does not "present *any barriers* to a manufacturer's ability to perform an audit of a covered entity." ADR Rule, 89 Fed. Reg. at 28,646 (emphasis added). The standard for audit approval—"reasonable cause"—is satisfied whenever "a reasonable person *could* believe that a covered entity *may have* violated [certain provisions of the 340B statute]." HRSA, *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). This standard can be met in various ways that do not require claims data. For example, it can be met by pointing to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity," or by citing "complaints from patients/other manufacturers about activities of a covered entity[.]" *Id.* at 65,406; *Or. Health & Sci. Univ. v. Engels*, Nos. 24-2184 (RC), 24-2187 (RC), 24-2268 (RC), 4-2563 (RC), 24-2998 (RC), 2025 WL 1707630, at *5 (D.D.C. June 17, 2025); *see, e.g.*, Ex. A, Decl. of Chantelle V. Britton, HRSA Office of Pharmacy Affairs, at ¶ 9 (Dec. 19, 2024) (noting HRSA's

approval of a manufacturer's audit request that was "based on a stark increase in [a provider's] utilization of the 340B program," not any data suggesting issues with specific claims).[13]

In addition, the 340B statute contemplates that manufacturers will collect specific evidence of covered entities' potential statutory violations *through an audit*—not as a prerequisite to conducting one. The statute expressly addresses a manufacturer's access to "the records of [a 340B] entity that directly pertain to the entity's compliance with [the 340B statute] with respect to drugs of the manufacturer." 42 U.S.C. § 256b(a)(5)(C). It provides that a manufacturer can access those records *via an* "*audit*." *Id.* (emphasis added). HRSA guidance similarly explains that, in the ADR process, manufacturers can establish covered entity violations because they "have the ability to gather needed information *through the audits*." ADR Rule, 89 Fed. Reg. at 28,652 (emphasis added). In contrast, HRSA's decision to *approve* a manufacturer audit is "preliminary [in] nature," *Or. Health & Sci. Univ.*, 2025 WL 1707630, at *5, and does not require that the manufacturer be able to prove any suspected violations using data regarding specific claims.

[13] As the Director of HRSA's Office of Pharmacy Affairs (OPA), Ms. Britton "oversee[s] the OPA staff that reviews requests by drugmakers that participate in the 340B Program to audit covered entities." Ex. A at ¶ 2. HRSA submitted Ms. Britton's declaration in *University of Wash. Med. Ctr. v. Becerra,* Case No. 1:24-cv-2998-RC (D.D.C) which is associated connection with *Or. Health & Sci. Univ. v. Engels*, Case No. 1:24-cv-2184-RC (D.D.C.).

PhRMA's concern that its members need claims data *before* any audit relies on a basic misunderstanding of the statutory scheme.

In fact, manufacturers seldom ask to conduct audits, and even when they do, they often fail to follow through with them. *See* Ex. A, Decl. of Chantelle Britton at ¶ 15 (noting that, "over the past decade-plus," HRSA approved 37 manufacturer audit requests, but only 18 audits were conducted).[14] And more fundamentally, *amici* are not aware of a single instance when HRSA has *ever* required, as a condition of authorizing a manufacturer audit, the sort of data that PhRMA now claims its members must be allowed to demand from covered entities.

Put simply, Act 143 is not an obstacle to pursuing the audit and ADR process under the 340B statute, and the Court should reject PhRMA's audit-based preemption theory.

3. *Act 143 does not interfere with 340B's remedial and enforcement regime.*

Furthermore, "[Act 143]'s enforcement scheme does not conflict with Section 340B's enforcement scheme." *AbbVie v. Fitch*, 2025 WL 2630900 at *8 (5th Cir.

[14] In contrast, HRSA itself audits approximately 200 covered entities each year for compliance with their 340B obligations. *See* U.S. Gov't Accountability Office, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 11 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.\ This includes "targeted" audits of covered entities when HRSA receives "information from stakeholders such as drug manufacturers about potential noncompliance." *Id.* at 11 n.22.

September 12, 2025) (unpublished). PhRMA contends that Act 143 "impermissibly attempts to permit private suits to enforce 340B" and creates a state-level enforcement regime that "conflicts with Congress's chosen scheme of exclusive federal oversight for 340B." Compl. ¶¶ 129-30. But Act 143 does not authorize private citizens or Attorney General Lopez to "enforce *340B*" or engage in "oversight *for 340B*." *Id.* ¶ 130 (emphasis added). Instead, Act 143 strictly provides for the enforcement of *its own* requirements—not the requirements of the 340B statute. *See* Act 143 § 4 (setting civil penalties for violations of specific subsections of Act 143); *AbbVie v. Fitch*, 2025 WL 2630900 at *8 (5th Cir. September 12, 2025) (unpublished).

> As the Eighth Circuit explained with respect to a similar Arkansas statute:
>
> > Act 1103 ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. Ark. Code Ann. § 23-92-604(c). The 340B Program, on the other hand, addresses discount pricing. ***Therefore, HHS has jurisdiction over different disputes***: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

PhRMA v. McClain, 95 F.4th at 1144 (emphasis added); Because the requirements that can be enforced under Hawaii (like the statute in *PhRMA v. McClain*) are different from the 340B program requirements, it does not conflict with the 340B program's enforcement regime. *AbbVie v. Fitch*, 24-60375 at 14 (5th Cir. September

12, 2025) (unpublished) ("[Act 143]'s enforcements scheme… does not concern the same subject matter as Section 340B and cannot be said to conflict with it."); *see PhRMA v. Murrill*, 2024 WL 4361597, at *8 ("[T]he Louisiana statute creates an enforcement mechanism, but that mechanism pertains solely to pharmaceutical companies' actions toward pharmacies who enter into contracts with covered entities under the Section 340B program. The Louisiana statute does not address the pharmaceutical companies' agreements with HHS or the pricing, diversion, or 'double dipping' restrictions addressed in the HHS' enforcement scheme.").

PhRMA argues that Act 143 requires Hawaii to "adjudicate[] multiple questions of federal law," such as determining who "qualif[ies]" as a 340B patient or whether a Medicaid rebate was already given on a particular drug, in state enforcement proceedings. Pls. MPI at 24-25. Not so. The Hawaii statute regulates the delivery of a 340B drug that has been purchased by a 340B hospital. Again, the question in any state action to enforce Act 143 would be whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy. If a manufacturer wants to argue that a drug was dispensed to a non-340B patient or that the company has been forced to pay a duplicate discount, then it must take that that argument to HRSA, not the state.

To the extent hypothetical pre-cursor questions about whether a drug is a 340B drug arise, those are easily answered by reference to the federal 340B statute, which

states are perfectly capable of reviewing. *Tafflin v. Levitt*, 493 U.S. 455, 467 (1990). And there is nothing improper about a state statute defining its reach by reference to federal law (and then imposing its own requirements)—or even a state statute whose "regulatory object" is a federal program. *See, e.g.*, *Chamber of Commerce*, 563 U.S. at 607–08 (rejecting preemption challenge to a state statute under which employers had to check their employees' *federal* immigration status using a specified *federal* database). Nor is it unusual for a state statute to expressly reference a federal program in defining its reach. *See, e.g.*, Haw. Rev. Stat. Ann. § 1B-1 (West) (defining an area as "rural" pursuant to the federal definition of rural).

PhRMA's mentions of diversion of drugs to non-eligible patients is also irrelevant to its challenge to Act 143. As discussed, the question in any state action arising under the Hawaii statute is whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy. So the issue of diversion, which relates to dispensing drugs to a non-340B patient, is outside the scope of the Hawaii law.[15] And this makes sense because if diversion were an issue, the federal 340B statute requires that HRSA determine whether the 340B drug purchase complied with federal law *after the fact* either through an audit or in the *post hoc* Alternative Dispute Resolution process. 42 U.S.C. §§ 256b(d)(2)(B)(iv) & (3). As

[15] For that same reason, it does not matter that Act 143 imposes different penalties than the 340B statute because Act 143 and the 340B statute regulate different conduct.

such, Act 143 and the federal 340B statute enforce different things and therefore do not raise the possibility of conflicting enforcement decisions.

CONCLUSION

For the foregoing reasons, Defendant's Motion to Dismiss should be granted.

DATED: Honolulu, Hawaii, September 15, 2025.

*/s/*Kevin W. Herring
KEVIN W. HERRING
ROBERT I. PARK
Ashford & Wriston, LLLP

WILLIAM B. SCHULTZ*
MARGARET M. DOTZEL*
COURTNEY CHRISTENSEN*
Zuckerman Spaeder LLP

Attorneys for Amicus Curiae
AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

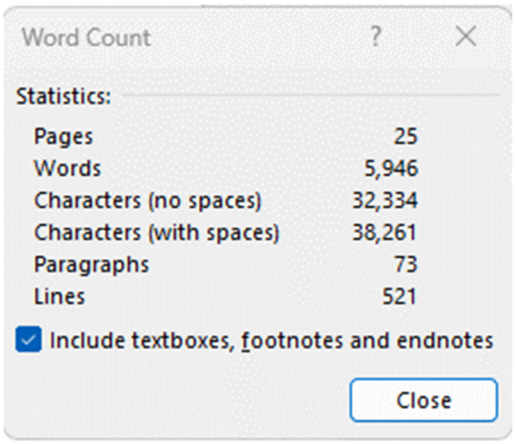
UNITED STATES DISTRICT COURT FOR THE DISTRICT OF HAWAII

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiffs, v. ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, Defendant.	CIVIL 1:25-cv-00292-SASP-KJM CERTIFICATE OF COMPLIANCE Judge: Hon. Shanlyn A.S. Park

CERTIFICATE OF COMPLIANCE

The proposed "BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS (DKT. 32) AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

(DKT. 11)" complies with the word-count limitation of L.R. 7.4(b) because it contains 5,946 words, exclusive of case caption, table of contents, and table of authorities, as counted by Microsoft Word. *See* L.R. 7.4(d) and 7.4(e).



DATED: Honolulu, Hawaii, September 15, 2025.

*/s/*Kevin W. Herring
KEVIN W. HERRING
ROBERT I. PARK
Ashford & Wriston, LLLP

WILLIAM B. SCHULTZ*
MARGARET M. DOTZEL*
COURTNEY CHRISTENSEN*
Zuckerman Spaeder LLP

Attorneys for Amicus Curiae AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiffs, v. ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, Defendant.	CIVIL 1:25-cv-00292-SASP-KJM CERTIFICATE OF SERVICE Judge: Hon. Shanlyn A.S. Park

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed and served via the Court's CM/ECF system.

DATED: Honolulu, Hawaii, September 15, 2025.

*/s/*Kevin W. Herring
KEVIN W. HERRING
ROBERT I. PARK
Ashford & Wriston, LLLP

WILLIAM B. SCHULTZ*
MARGARET M. DOTZEL*
COURTNEY CHRISTENSEN*
Zuckerman Spaeder LLP

Attorneys for Amicus Curiae AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, HEALTHCARE ASSOCIATION OF HAWAII, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS